

100



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,185	02/25/2002	Thomas Dag Horn	023533-0144	4869
22428	7590	04/09/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/081,185

Applicant(s)

HORN ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

Art Unit: 1642

### DETAILED ACTION

Claims 1-47 are pending.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 10, 27, 40-41, 46-47 as specifically drawn to a pharmaceutical composition comprising a combination of antigens wherein said antigens **are** candida, trichophyton and mumps antigens, classified in Class 424, subclass 201.1, 274.1.

II. Claims 1-9, 13-15, 33-39, 42-45, as specifically drawn to a pharmaceutical composition comprising at least **2** antigens and no immunogenic additives, classified in Class 424, subclass 201.1, 274.1:

- a) candida and trichophyton
- b) candida and mumps
- c) mumps and trichophyton
- d) bacterial and candida
- e) bacterial and mumps
- f) bacterial and trichophyton

Upon election of Group II, applicant must further elect ONE invention from those listed in groups a-f above as each composition is an independent or distinct invention not a species. Applicant is reminded that any claims not reading upon the elected invention will be withdrawn as drawn to a non-elected group.

III. Claims 1-9, 11-14, 17, 34-39, 42-45 as specifically drawn to a pharmaceutical composition comprising at least **2** antigens and one CSF, classified in Class 424, subclass 201.1, 274.1, 198.1:

- a) candida and trichophyton + 1 CSF
- b) candida and mumps + 1CSF
- c) mumps and trichophyton + 1 CSF
- d) bacterial and candida + 1 CSF
- e) bacterial and mumps + 1 CSF
- f) bacterial and trichophyton +1 CSF

Art Unit: 1642

**Upon election of Group III, applicant must further elect ONE invention from those listed in groups a-f above as each composition is an independent or distinct invention not a species. Applicant is reminded that any claims not reading upon the elected invention will be withdrawn as drawn to a non-elected group**

IV. Claims 1-9, 11-16, 34-39, 42-45 as specifically drawn to a pharmaceutical composition comprising at least 2 antigens and one cytokine, classified in Class 424, subclass 201.1, 274.1, 198.1:

- a) candida and trichophyton + 1 cytokine
- b) candida and mumps + 1 cytokine
- c) mumps and trichophyton + 1 cytokine
- d) bacterial and candida + 1 cytokine
- e) bacterial and mumps + 1 cytokine
- f) bacterial and trichophyton + 1 cytokine

**Upon election of Group IV, applicant must further elect ONE invention from those listed in groups a-f above as each composition is an independent or distinct invention not a species. Applicant is reminded that any claims not reading upon the elected invention will be withdrawn as drawn to a non-elected group.**

V. Claims 18-26, 28-32, as specifically drawn to a pharmaceutical composition comprising at least 1 antigen and one CSF, classified in Class 424, subclass 201.1, 274.1, 198.1:

- a) candida + 1 CSF
- b) trichophyton + 1 CSF
- c) mumps + 1 CSF
- d) bacterial + 1 CSF

**Upon election of Group V, applicant must further elect ONE invention from those listed in groups a-d above as each composition is an independent or distinct invention not a species. Applicant is reminded that any claims not reading upon the elected invention will be withdrawn as drawn to a non-elected group**

VI. Claims 18-26, 28-32, as specifically drawn to a pharmaceutical composition comprising at least 1 antigen and one cytokine, classified in Class 424, subclass 201.1, 274.1, 198.1:

- a) candida + 1 cytokine

Art Unit: 1642

- b) trichophyton + 1 cytokine
- c) mumps + 1 cytokine
- d) bacterial + 1 cytokine

**Upon election of Group VI, applicant must further elect ONE invention from those listed in groups a-d above as each composition is an independent or distinct invention not a species. Applicant is reminded that any claims not reading upon the elected invention will be withdrawn as drawn to a non-elected group**

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-VI represent separate and distinct products that are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions. For example, the invention of Group I consists of a combination of three unrelated antigens which is independent and or distinct from a pharmaceutical combination comprising at least one antigen or a least two unrelated antigens. For example, the search and examination of at least two viral and fungal antigens in pharmaceutical formulation would not necessarily include the search and examination of a pharmaceutical composition comprising two or three chemically distinct bacterial antigens. Further, each type of antigen (candida or bacterial or trichophyton or mumps) formulation represents an independent pharmaceutical composition, as each antigen or combination thereof is chemically distinct, nonobvious, and unrelated in structure and function. Furthermore, the addition of specific immunogenic modulators provides for distinctly different pharmaceutical compositions with different effects. Finally, although all of the groups are similar in classification and are drawn to pharmaceutical compositions, the number of potential compositions is broadly inclusive of *any* number of viral, bacterial, or fungal antigens which

Art Unit: 1642

invokes a high burden of search in the literature. Each individual composition must not only be searched separately in the literature, but also must be individually examined for patentability under 35 USC 101 and 112 1<sup>st</sup> paragraphs. Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

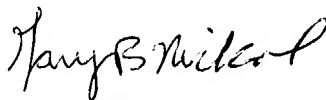
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

April 8, 2004

  
**GARY NICKOL**  
**PRIMARY EXAMINER**